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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,048	08/30/2001	Mawaheb M. EL-Naggar		8472

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EXAMINER

KWON, BRIAN YONG S

ART UNIT PAPER NUMBER

1614

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,048

Applicant(s)

EL-NAGGAR ET AL.

Examiner

Brian S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Summary of Action

- I. The objection of claim 5 is not maintained in light of the amendment.
- II. The rejection of claims 1 and 4 under 35 USC 112, second paragraph, is not maintained in light of the amendment.
- III. The rejection of claims 1 and 5 under 35 USC 103(a) as being unpatentable over Lai et al. (US 6306842 B1) in view of Ares et al. (US 5399584), or if necessary further in view of Anderson et al. (US 6248341 B1) is maintained for the reason of the record.

Status of Application

1. By an amendment filed June 30, 2003, claims 2-4 have been cancelled and claims 6-7 have been newly added.
2. The newly submitted claims 6-7 are directed to an invention that is drawn to a non-elected invention (see pages 2-3 of O.A. mailed on April 10, 2002). Accordingly, claims 6-7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al. (US 6306842 B1) in view of Ares et al. (US 5399584), or if necessary further in view of Anderson et al. (US 6248341 B1)

This rejection is analogous to the original rejection.

Response to Arguments

Applicant's arguments filed June 30, 2003 have been fully considered but they are not persuasive.

Applicant's argument takes position that Lai does not teach or suggest the combination administration of different doses of NSAIDS and COX2 inhibitors because nowhere in Lai is taught to administer "non-covalently linked, NSAIDS and COX2 inhibitors" nor "NSAIDS in low dose combination with a COX2 inhibitor".

The examiner disagrees. There is no statement or indication in the instant claims, however that said combination must be essentially in the form of "non-covalently linked, NSAIDS and COX2 inhibitor". Thus, claims seem to include method wherein said combination is administered in the formulations containing conjugates of NSAIDs and COX2 inhibitors and flavonoids. Therefore, the referenced teaching of "covalently linked NSAIDs and COX2 inhibitors combination" (in combination with Ares or Anderson) makes obvious the claimed invention. Although Lai does not specifically disclose the claimed low dose of aspirin (70-85mg), those of ordinary skill in the art would have

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readily optimized effective dosages as determined by good medical practice and the clinical condition of the individual patient. It is considered that determination of appropriate dosage for treatment involving the claimed invention is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed herein.

Applicant's argument takes position that the disclosed 100mg/kg acetylsalicylic acid in "Test Method II" of Ares is much higher than Applicant's dose of 70-85mg, thus, Ares actually teaches away from Applicant's invention. This argument is found not persuasive at all. Unlike applicant's allegation, the tested acetylsalicylic acid amount is actually lower than 70-85mg. If 100mg/kg of acetylsalicylic acid is administered to male Sprague Dawley rats (approximate weight range of 200-350gm), the actual dose of aspirin in the Test should be in range of between 20-35mg. Although Ares discloses the use of 100mg/kg of acetylsalicylic acid as the specific embodiment of the invention, the examiner does not believe that teaching of Ares is only limited to application of said composition to rat model. Rather, Ares teaches that the methods of the subject invention include administering to a human or lower animal (column 6, lines 32-34). Those of ordinary skill in the art would have readily understood that the administered dose amount of acetylsalicylic acid would be (proportionally) increased when body of weight of the treatment recipient group (e.g., dog, cat, human) is increased. Therefore, those of ordinary skill in the art would have known that the claimed "low dose aspirin in the amount of 70-85mg" is well within the prior art method.

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Applicant's argument takes position that Anderson merely recites the use of flavonoids to treat angiogenesis. The examiner disagrees. Unlike applicant's allegation, Anderson also teaches the use of flavonoids for the treatment of inflammatory conditions including rheumatoid arthritis and psoriasis (column 1, lines 51-52; column 2, lines 52-55). Therefore, the examiner maintains that Anderson provides ample motivation to modify the teaching of Lai.

In response to applicant's argument that there is no suggestion or motivation to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

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advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

VICKIE KIM
PRIMARY EXAMINER



Brian Kwon
Patent Examiner
AU 1614